General

Guideline Title

Atrial fibrillation and heart valve disease: self-monitoring coagulation status using point-of-care coagulometers (the CoaguChek XS system and the INRatio2 PT/INR monitor).

Bibliographic Source(s)

National Institute for Health and Care Excellence (NICE). Atrial fibrillation and heart valve disease: self-monitoring coagulation status using point-of-care coagulometers (the CoaguChek XS system and the INRatio2 PT/INR monitor). London (UK): National Institute for Health and Care Excellence (NICE); 2014 Sep. 47 p. (Diagnostics guidance; no. 14).

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Recommendations

Major Recommendations

The CoaguChek XS system is recommended for self-monitoring coagulation status in adults and children on long-term vitamin K antagonist therapy who have atrial fibrillation or heart valve disease if:

- The person prefers this form of testing and
- The person or their carer is both physically and cognitively able to self-monitor effectively.

The InRatio2 prothrombin time/international normalized ratio (PT/INR) monitor is recommended for self-monitoring coagulation status in adults and children on long-term vitamin K antagonist therapy who have atrial fibrillation or heart valve disease if:

- The person prefers this form of testing and
- The person or their carer is both physically and cognitively able to self-monitor effectively.
  Although there is greater uncertainty of clinical benefit for the InRatio2 PT/INR monitor than for the CoaguChek XS system, the evidence indicates that the precision and accuracy of both monitors are comparable to laboratory-based INR testing.

Patients and carers should be trained in the effective use of the CoaguChek XS system or the INRatio2 PT/INR monitor and clinicians involved in their care should regularly review their ability to self-monitor.

Equipment for self-monitoring should be regularly checked using reliable quality control procedures, and by testing patients' equipment against a

healthcare professional's coagulometer which is checked in line with an external quality assurance scheme. Ensure accurate patient records are kept and shared appropriately.

For people who may have difficulty with or who are unable to self-monitor, such as children or people with disabilities, their carers should be considered to help with self-monitoring.

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

- Atrial fibrillation
- Heart valve disease
- Venous thromboembolism
- Haemorrhage

Guideline Category

Evaluation

Management

Prevention

Technology Assessment

Clinical Specialty

Cardiology

Emergency Medicine

Family Practice

Hematology

Internal Medicine

Pediatrics

Preventive Medicine

Intended Users

Advanced Practice Nurses

Nurses

Physician Assistants

Physicians

Guideline Objective(s)

To evaluate the clinical and cost-effectiveness of using the CoaguChek XS system and the INRatio2 prothrombin time/international normalized ratio (PT/INR) monitor for self-monitoring (self-testing or self-managing) coagulation status in people on long-term vitamin K antagonist therapy who have atrial fibrillation or heart valve disease

Target Population

Children and adults on long-term vitamin K antagonist therapy who have atrial fibrillation or heart valve disease

Interventions and Practices Considered

Self-monitoring coagulation status using point-of-care coagulometers (the CoaguChek XS system and the INRatio2 prothrombin time/international normalized ratio [PT/INR] monitor)

Major Outcomes Considered

- Clinical outcomes
  - Frequency of bleeds or blood clots
  - Morbidity (e.g., thromboembolic and cerebrovascular events) and mortality from internal normalized ratio (INR) testing and vitamin K antagonist therapy
  - Adverse events from INR testing, false test results, vitamin K antagonist therapy and sequelae
- Patient reported outcomes
  - People's anxiety associated with waiting time for results and not knowing their current coagulation status and risk
  - Acceptability of the tests
  - Health related quality of life
- Intermediate outcomes
  - Time and INR values in therapeutic range
  - Test failure rate
  - Time to test result
  - Patient compliance with testing and treatment
  - Frequency of testing
  - Frequency of visits to primary or secondary care clinics
- Cost-effectiveness

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Note from the National Guideline Clearinghouse (NGC): The National Institute for Health and Care Excellence (NICE) commissioned an External Assessment Group to perform a systematic literature review on the technology considered in this diagnostics guidance and prepare a Diagnostics Assessment Report (DAR). The DAR for this guidance was prepared by the Aberdeen Health Technology Assessment (HTA) group (see the "Availability of Companion Documents" field).

Assessment Design and Results — Clinical Effectiveness

Methods for Standard Systematic Review of Effectiveness

Identification of Studies

Comprehensive electronic searches were undertaken to identify relevant reports of published studies. Highly sensitive search strategies were designed using both appropriate subject headings and relevant text word terms, to retrieve randomised controlled trials (RCTs) evaluating the point-of-care tests under consideration for the self-monitoring of anticoagulation therapy. A 2007 systematic review with similar objectives to those of the current assessment was identified in the Cochrane Library. Since extensive literature searches had already been undertaken for the preparation of this systematic review, the literature searches for the current assessment were run in May 2013 for the period '2007-to date' to identify newly published reports. All RCTs included in the Cochrane review were obtained and included for full-text assessment. Searches were restricted to publications in English. MEDLINE, MEDLINE In Process, EMBASE, Biosis, Science Citation Index, and Cochrane Controlled Trials Register (CENTRAL) were searched for primary studies while the Cochrane Database of Systematic Reviews (CDSR), the Database of Abstracts of Reviews of Effects (DARE) and the HTA database were searched for reports of evidence syntheses.

Reference lists of all included studies were perused in order to identify additional potentially relevant reports. The expert panel provided details of any additional potentially relevant reports.

Searches for recent conference abstracts (2011 to 2013) were also undertaken and included the annual conferences of the American Society of Hematology (ASH), the European Hematology Association (EHA) and the International Society on Thrombosis and Haemostasis (ISTH) as well as the proceedings of the 12th National Conference on Anticoagulant Therapy. Ongoing studies were identified through searching Current Controlled Trials, Clinical Trials, World Health Organization (WHO) International Clinical Trials Registry and NIH Reporter. Websites of professional organisations and health technology agencies were checked to identify additional reports. Full details of the search strategies used are presented in Appendix 1 in the DAR.

Inclusion and Exclusion Criteria

The studies fulfilling the following criteria were included in this assessment:

Population

People with atrial fibrillation or heart valve disease for whom long-term vitamin K antagonist therapy was required.

Setting

Self international normalized ratio (INR) monitoring supervised by primary or secondary care.

Interventions

The point-of-care devices considered in this assessment were:

- CoaguChek system
- INRatio2 prothrombin time (PT)/INR monitor
- ProTime Microcoagulation system

Comparators

The comparator considered in this assessment was standard practice, which consisted of INR monitoring managed by healthcare professionals. INR monitoring can be carried out in primary care, in secondary care or in a "shared provision" setting:

- Primary care - INR monitoring can be carried out in primary care anticoagulant clinics using point-of-care tests or laboratory analysers. In the latter, blood samples are sent to a central laboratory based at a hospital (shared provision)
- Secondary care - INR monitoring can be carried out in hospital-based anticoagulant clinics using point-of-care tests or laboratory analysers.

Outcomes

The following outcomes were considered:

Clinical outcomes:

- Frequency of bleeds or blood clots

- Morbidity (e.g., thromboembolic and cerebrovascular events) and mortality from INR testing and vitamin K antagonist therapy
- Adverse events from INR testing, false test results, vitamin K antagonist therapy and sequelae

Patient reported outcomes:

- People's anxiety associated with waiting time for results and not knowing their current coagulation status and risk
- Acceptability of the tests
- Health related quality of life

Intermediate outcomes:

- Time and INR values in therapeutic range
- Test failure rate
- Time to test result
- Patient compliance with testing and treatment
- Frequency of testing
- Frequency of visits to primary or secondary care clinics

Study Design

Priority was given to RCTs assessing the effectiveness of the CoaguChek system, the INRatio2 PT/INR monitor, and the ProTime Microcoagulation system. In the absence of RCTs, non-randomised studies (including observational studies) were considered, providing they included relevant outcomes for this assessment. Systematic reviews were used as source for identifying additional relevant studies.

Studies were excluded if they did not meet the pre-specified inclusion criteria and, in particular, the following types of report were not deemed suitable for inclusion:

- Biological studies
- Reviews, editorials and opinions
- Case reports
- Non-English language reports
- Conference abstracts published before 2012

Two reviewers independently screened the titles and abstracts of all citations identified by the search strategies. Full-text copies of all studies deemed to be potentially relevant were obtained and assessed independently by two reviewers for inclusion. Any disagreements were resolved by discussion or arbitration by a third reviewer.

Assessment of Cost-effectiveness

Systematic Review of Existing Cost-effectiveness Evidence

Initial scoping searches revealed a number of previous systematic reviews of economic studies evaluating point-of-care testing devices for people receiving long-term vitamin K antagonist therapy. Further systematic searches of MEDLINE, MEDLINE In-Process, EMBASE, Science Citation Index, Health Management Information Consortium (HMIC), National Institute for Health Research (NIHR) Economic Evaluations Database (NEED) and the HTA Databases were undertaken to identify any further relevant studies. The search strategies are detailed in Appendix 1 in the DAR.

Number of Source Documents

Assessment Design and Results — Clinical Effectiveness

A total of 658 records were retrieved for the assessment of the clinical effectiveness of the point-of-care tests under investigation. After screening titles and abstracts, 563 were excluded and full text reports of 120 potentially relevant articles were obtained for further assessment including 25 full-text papers from the 18 trials included in a Cochrane systematic review. In total, 26 randomised controlled trials (RCTs) (published in 45 papers) met the inclusion criteria and were included in the clinical effectiveness section of this assessment. Three of the 26 included studies were randomised crossover trials, while the remaining studies were parallel group RCTs. Figure 1 in the Diagnostics Assessment Report (DAR) (see the "Availability of Companion Documents" field) shows the flow diagram outlining the selection process. Appendix 5 in the DAR lists the number of studies excluded after full-text assessment and the reasons for their exclusion.

Assessment of Cost-effectiveness

- The searches identified 12 economic evaluations of potential relevance to the scope of this assessment.
- A *de novo* economic model was submitted.

Methods Used to Assess the Quality and Strength of the Evidence

Expert Consensus

Rating Scheme for the Strength of the Evidence

Not applicable

Methods Used to Analyze the Evidence

Meta-Analysis

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Note from the National Guideline Clearinghouse (NGC): The National Institute for Health and Care Excellence (NICE) commissioned an External Assessment Group to perform a systematic literature review on the technology considered in this diagnostics guidance and prepare a Diagnostics Assessment Report (DAR). The DAR for this guidance was prepared by the Aberdeen Health Technology Assessment (HTA) group (see the "Availability of Companion Documents" field).

Assessment Design and Results — Clinical Effectiveness

Methods for Standard Systematic Review of Effectiveness

Data Extraction Strategy

A data extraction form was designed and piloted for the purpose of this assessment (see Appendix 2 in the DAR). One reviewer extracted information on study design, characteristics of participants, settings, characteristics of interventions and comparators, and relevant outcome measures. A second reviewer crosschecked the details extracted by the first reviewer. There was no disagreement between reviewers.

Assessment of Risk of Bias in Included Studies

A single reviewer assessed the risk of bias of the included studies and findings were crosschecked by a second reviewer. There were few disagreements which were resolved by consensus or arbitration by a third reviewer. The reviewers were not blinded to the names of studies' investigators, institutions, and journals. Studies were not included or excluded purely on the basis of their methodological quality. The risk of bias assessment for all included randomised controlled trials (RCTs) was performed using the Cochrane Risk of Bias tool (see Appendix 3 in the DAR). Critical assessments were made separately for all main domains: selection bias ('random sequence generation', 'allocation concealment'), detection bias ('blinding of outcome assessor'), attrition bias ('incomplete outcome data') and reporting bias ('selective reporting'). The 'blinding of participants and personnel' was not considered relevant for this assessment due to the nature of intervention being studied (i.e., patient performing the test themselves or under supervision of health care professionals). However, the Assessment Group collected information related to the blinding of outcome assessors, which was considered relevant to the assessment of risk of bias.

Each included study was judged as 'low risk of bias', 'high risk of bias' or as 'unclear risk of bias' according to the criteria for making judgments about risk of bias described in the Cochrane Handbook for Systematic Reviews of Interventions. Adequate sequence generation, allocation concealment, and blinding of outcome assessor were identified as key domains for the assessment of the risk of bias of the included trials.

Data Analysis

For dichotomous data (e.g., bleeding events, thromboembolic events, mortality), relative risk (RR) was calculated. For continuous data (e.g., time in therapeutic range), weighted mean difference (WMD) was calculated. Where standard deviations were not given, the Assessment Group calculated them using test statistics wherever possible. The RR and WMD effect sizes were meta-analysed as pooled summary effect sizes using the Mantel-Haenszel method and the inverse-variance method, respectively. Confidence intervals were also calculated (95% CIs). To estimate the summary effect sizes, both fixed effects and random effects models were used with RR and WMD. In the absence of clinical and/or statistical heterogeneity, the fixed effects model was selected as the model of choice while the random effects model was used to crosscheck the robustness of the fixed effects model. However, in the presence of either clinical or statistical heterogeneity, the random effects model was chosen as the preferred method for pooling the effect sizes, as in this latter situation, the fixed effect method is not considered appropriate for combining the results of included studies. Heterogeneity across studies was measured by means of the Chi-squared statistic and also by the I-squared statistic, which describes the percentage of variability in study effects that is explained by real heterogeneity rather than chance. It is worth noting that, for bleeding and thromboembolic events, the Assessment Group used the total number of participants who were actually analysed as denominator in the analyses. In contrast, for mortality, they used the total number of participants randomised as denominator because participants could have died due to any causes after randomisation but before entering the self-monitoring programme.

Apart from the pre-specified subgroups analysis according to the type of anticoagulation therapy management (self-testing and self-management), the Assessment Group performed a post-hoc subgroup analysis according to the type of the target clinical condition (i.e., atrial fibrillation, heart valve disease, and mixed clinical indication) and one according to the type of service provision for anticoagulation management (i.e., primary care, secondary care, and shared provision). Where trials had multiple arms contributing to different subgroups, the control group was subdivided into two groups to avoid a unit of analysis error.

Sensitivity analyses were planned in relation to some of the study design characteristics. The methodological quality (low/high risk of bias), and the different models of the CoaguChek system were identified at protocol stage as relevant aspects to explore in sensitivity analyses. In addition to those pre-specified in the protocol, a sensitivity analysis was performed by excluding the studies conducted in the UK.

Review Manager software (Review Manager 5.2, 2012) was used for data management and all relevant statistical analyses for this assessment. Where it proved unfeasible to perform a quantitative synthesis of the results of the included studies, outcomes were tabulated and described in a narrative way.

See Section 3 in the DAR for more information on clinical effectiveness analysis.

Assessment of Cost-effectiveness

Independent Economic Assessment

A *de novo* economic model was developed in TreeAge Pro (TreeAge Software, Williamstown, MA, 2013). The model was designed to assess the cost-effectiveness of self-monitoring (self-testing and self-management) using alternative point-of-care devices: CoaguChek XS system, INRatio2 prothrombin time/international normalized ratio (PT/INR) monitor, and ProTime Microcoagulation system.

The model was populated using data derived from the systematic clinical effectiveness review, other focused reviews to inform key parameters (e.g. baseline risks), routine sources of cost data, and where necessary some study specific cost estimates based on expert opinion. The model was built and analysed in accordance with the NICE reference case for the evaluation of diagnostic tests and devices.

Methods

Relevant Patient Population(s)

The model compared the alternative monitoring strategies for a hypothetical cohort of people with atrial fibrillation or an artificial heart valve. These two groups represent the majority of people on long-term vitamin K antagonist therapy. While self-monitoring of INR is relevant to other patient groups, including those with venous thrombotic embolism, there was insufficient data to explicitly model cost-effectiveness for all groups individually. Furthermore, the majority of studies informing the relative effects of alternative monitoring strategies were derived from trials including predominantly people with atrial fibrillation and/or an artificial heart valve. Therefore, the base case modelling exercise was carried out for a mixed cohort consisting of people with one or other of these two conditions.

Monitoring Strategies to Be Evaluated

The economic model incorporated the pathways of care that individuals currently follow under standard practice in the National Health Service (NHS), as well as proposed new pathways for self-testing and self-management (informed by a review of current guidelines and expert opinion). Current practice was dichotomised in the model as standard monitoring in primary care and standard monitoring in secondary care. In the base case analysis, the proportional split between standard primary and secondary care INR monitoring was taken from the manufacturer's submission

for NICE technology appraisal 256 (TA256) . Based on a survey of providers in England and Wales carried out in 2011, it was estimated that 66.45% and 33.55% of warfarin monitoring appointments were managed in a primary and secondary care setting, respectively. These figures were accepted by the independent evidence review group and appraisal committee for NICE TA256.

In terms of self-monitoring, the model incorporated both self-testing and self-management strategies using the alternative devices identified in the scope. However, the cost-effectiveness of self-monitoring was assessed as a whole, and it was assumed in the base case analysis that 50% of people would self-test whilst 50% would self-manage. These proportions were varied in sensitivity analysis. Self-testing and self-management strategies were costed separately for each device based on the assumption that self-testing people phone in their results from all tests undertaken, while self-managing people manage their dosing independently. In reality, some self-monitoring people are likely to fall somewhere in between these two strategies, and several alternative scenarios were also assessed.

Framework (Method of Synthesis)

The alternative monitoring pathways, informed by review of previous guidance and expert opinion, were embedded in a Markov model simulating the occurrence of adverse events over time. The adverse events included in the model were ischaemic stroke (minor, non-disabling, and major, disabling or fatal), systemic embolism (SE), minor haemorrhage, and major haemorrhage (intra-cranial haemorrhage [ICH], including haemorrhagic stroke [HS], gastrointestinal [GI] bleed, and others). Systemic embolism was treated as a transient event within the model, such that people surviving this event returned to baseline levels of quality of life and did not incur on-going costs and morbidity. Minor haemorrhage was handled in the same way. Ischemic stroke and ICH were assigned post event states associated with additional costs and quality of life decrements.

The model simulated transitions between the discrete health states, and accumulated costs and quality adjusted life years on a quarterly (three-month) cycle. Within each three-month cycle, the simulated cohort was exposed to a risk of the aforementioned events as well as death from other causes. A constraint was applied whereby simulated people could only experience one event per cycle. A further simplifying structural assumption was applied, such that following a major ischaemic stroke or ICH, no further events were explicitly modelled. However, all-cause mortality was inflated following these events to account for the increased risk of death.

See Section 4 in the DAR for detailed information on cost-effectiveness analysis.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Developing Recommendations

After reviewing the evidence the Diagnostic Advisory Committee (DAC) agrees draft recommendations on the use of the technology in the National Health Service (NHS) in England. When formulating these recommendations, the Committee has discretion to consider those factors it believes are most appropriate to the evaluation. In doing so, the Committee has regard to any relevant provisions of the National Institute for Health and Care Excellence's (NICE's) Directions, set out by the Secretary of State for Health, and legislation on human rights, discrimination and equality. In undertaking evaluations of healthcare technologies, NICE takes into account the broad balance of clinical benefits and costs, the degree of clinical need of patients under consideration, any guidance issued to the NHS by the Secretary of State that is specifically drawn to the attention of NICE by the Secretary of State, and any guidance issued by the Secretary of State, and the potential for long-term benefits to the NHS of innovation.

The Committee takes into account advice from NICE on the approach it should take to making scientific and social value judgements. Advice on social value judgements is informed in part by the work of NICE's Citizens Council.

The Committee takes into account how its judgements have a bearing on distributive justice or legal requirements in relation to human rights, discrimination and equality. Such characteristics include, but are not confined to: race, gender, disability, religion or belief, sexual orientation, gender reassignment and pregnancy or maternity.

The Committee considers the application of other Board-approved NICE methods policies, such as the supplementary guidance on discounting and the end-of-life criteria, if they are relevant to the evaluation.

Because the Programme often evaluates new technologies that have a thin evidence base, in formulating its recommendations the Committee balances the quality and quantity of evidence with the expected value of the technology to the NHS and the public.

The credibility of the guidance produced by NICE depends on the transparency of the DAC's decision-making process. It is crucial that the DAC's decisions are explained clearly, and that the contributions of registered stakeholders and the views of members of the public are considered. The reasoning behind the Committee's recommendations is explained, with reference to the factors that have been taken into account.

The language and style used in the documents produced by the Committee are governed by the following principles:

- Clarity is essential in explaining how the DAC has come to its conclusions.
- The text of the documents does not need to reiterate all the factual information that can be found in the information published alongside the guidance. This needs careful judgement so that enough information and justification is given in the recommendations to enable the reader to understand what evidence the DAC considered and, if appropriate, who provided that evidence.

The Committee may take into account factors that may provide benefits to the NHS or the population, such as patient convenience. It may also consider costs and other positive or negative impacts on the NHS that may not be captured in the reference-case cost analysis, such as improved processes.

Rating Scheme for the Strength of the Recommendations

Not applicable

Cost Analysis

Systematic Review of Cost-effectiveness Evidence

The systematic review identified 12 relevant economic evaluations. All of these evaluations compared international normalized ratio (INR) self-monitoring strategies with standard care and were assessed against the National Institute for Health and Care Excellence (NICE) reference case by the External Assessment Group. The results of the studies included in the systematic review varied widely and showed that the cost-effectiveness of self-monitoring was dependent on a number of key factors. Refer to the original guideline document for additional discussion of the systematic review of economic evaluations.

Economic Analysis

The External Assessment Group developed a de novo economic model designed to assess the cost-effectiveness of self-monitoring (self-managing and self-testing) coagulation status using 2 different point-of-care coagulometers: the CoaguChek XS system and the INRatio2 prothrombin time (PT)/INR monitor.

Base-Case Analysis

For the purposes of decision-making, the incremental cost-effectiveness ratios (ICERs) per quality-adjusted life year (QALY) gained were considered.

The results indicated that over a 10-year period, introducing self-monitoring would reduce the proportion of people experiencing a thromboembolic event by 2.5%, while slightly increasing the proportion having a major haemorrhagic event by 1.4%.

The predicted monitoring costs were higher with self-monitoring compared with standard monitoring, but the total health and social care costs were similar and in some cases lower. The QALY gains were greater for self-monitoring than standard monitoring. For all of the self-monitoring coagulometers there was a QALY gain of 0.027 compared with standard monitoring. Self-monitoring with the INRatio2 PT/INR monitor was £29 cheaper than standard monitoring. Self-monitoring with the CoaguChek XS system was £37 more expensive than standard monitoring. Therefore, in the base-case scenario, the self-monitoring strategies compared favourably with standard care. The INRatio2 PT/INR monitor dominated standard monitoring in the analysis because it was less costly and more effective. The ICER for the CoaguChek XS system was £319 per QALY gained compared with standard monitoring. The lower cost of the INRatio2 PT/INR monitor and testing strips, coupled with the assumption of equivalent clinical effectiveness, meant that the INRatio2 PT/INR monitor also dominated the CoaguChek XS system. However, it should be noted that no direct evidence of clinical effectiveness was identified exclusively for the INRatio2 PT/INR monitor from the systematic review.

Analysis of Alternative Scenarios

Subgroup analyses showed the cost-effectiveness of self-monitoring compared with standard care, stratified by indication (atrial fibrillation and artificial heart valves) and cohort age. Self-monitoring in a '65 years old with atrial fibrillation' cohort was estimated to cost £2574 per QALY

gained when using the INRatio2 PT/INR monitor and £4160 per QALY gained when using the CoaguChek XS system, compared with standard monitoring. For a '65 years old with artificial heart valve' cohort, self-monitoring with the INRatio2 PT/INR monitor and the CoaguChek XS system was found to be more effective and less costly (dominant) compared with standard monitoring.

A further analysis was carried out for the atrial fibrillation cohort using the baseline risks seen for participants with better INR control in standard care, assuming a constant relative risk reduction for thromboembolic events associated with self-monitoring. As the INR time in therapeutic range increased in the control group, and the baseline risk of thromboembolic events consequently dropped, the cost-effectiveness of self-monitoring also decreased. However, the ICERs for the CoaguChek XS system and the INRatio2 PT/INR monitor only rose above £20,000 per QALY gained when the baseline time in therapeutic range was set at greater than 72.6%.

See sections 5 and 6 in the original guideline document for additional discussion of cost-effectiveness and Committee considerations for use of point-of-care coagulometers.

Method of Guideline Validation

External Peer Review

Description of Method of Guideline Validation

The National Institute for Health and Care Excellence (NICE) sends the Diagnostics Assessment Report (DAR), with any confidential material removed, to registered stakeholders for comment. Stakeholders have 10 working days to return comments. Models supporting the DAR are made available to registered stakeholders on request during this period.

NICE presents anonymised registered stakeholder comments on the DAR, along with any responses from NICE or the External Assessment Group (EAG), to the Committee and later publishes these comments on its website.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of evidence supporting the recommendations is not specifically stated.

The Diagnostics Advisory Committee considered clinical and cost-effectiveness evidence from a systematic review of point-of-care tests (CoaguChek system, INRatio2 PT/INR monitor and ProTime Microcoagulation system) performed by an External Assessment Group.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Use of the CoaguChek XS system and the INRatio2 prothrombin time/international normalized ratio (PT/INR) monitor may reduce the frequency of visits to hospital or clinics for patients and enable them to be monitored more regularly. This may improve health outcomes by enabling the dose of therapy to be adjusted more accurately, thereby avoiding adverse events that can result from an over- or under-dose of long-term vitamin K antagonist therapy, such as stroke and major haemorrhage.

Potential Harms

Not stated

Qualifying Statements

Qualifying Statements

- This guidance represents the view of the National Institute for Health and Care Excellence (NICE), which was arrived at after careful consideration of the evidence available. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. However, the guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.
- Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way which would be inconsistent with compliance with those duties.

Implementation of the Guideline

Description of Implementation Strategy

National institute of Health and Care Excellence (NICE) has developed tools (see also the "Availability of Companion Documents" field), in association with relevant stakeholders, to help organisations put this guidance into practice.

Implementation Tools

Foreign Language Translations

Mobile Device Resources

Patient Resources

Resources

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Living with Illness

Staying Healthy

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

National Institute for Health and Care Excellence (NICE). Atrial fibrillation and heart valve disease: self-monitoring coagulation status using point-of-care coagulometers (the CoaguChek XS system and the INRatio2 PT/INR monitor). London (UK): National Institute for Health and Care Excellence (NICE); 2014 Sep. 47 p. (Diagnostics guidance; no. 14).

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2014 Sep

Guideline Developer(s)

National Institute for Health and Care Excellence (NICE) - National Government Agency [Non-U.S.]

Source(s) of Funding

National Institute for Health and Care Excellence (NICE)

Guideline Committee

Diagnostics Advisory Committee

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Financial Disclosures/Conflicts of Interest

Committee members are required to submit a declaration of interests on appointment, in every year of their tenure, and at each Committee

meeting, in line with the National Institute for Health and Care Excellence's (NICE's) code of practice for declaring and dealing with conflicts of interest.

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Guideline Availability

Electronic copies: Available from the National Institute for Health and Care Excellence (NICE) Web site . Also available for download as a Kindle or EPUB ebook from the NICE Web site .

Availability of Companion Documents

The following are available:

- Sharma P, Scotland G, Cruickshank M, Tassie E, Fraser C, Burton C, Croal B, Ramsay CR, Brazzelli M. Clinical and cost-effectiveness of point-of-care tests (CoaguChek system, INRatio2 PT/INR monitor and ProTime Microcoagulation system) for the self-monitoring of the coagulation status of people receiving long-term vitamin K antagonist therapy compared with standard UK practice: systematic review and economic evaluation. Diagnostics assessment report. Aberdeen (UK): Aberdeen Health Technology Assessment (HTA) Group, Institute of Applied Health Sciences, University of Aberdeen; 2013. 221 p. Electronic copies: Available in from the National Institute for Health and Care Excellence (NICE) Web site .
- Atrial fibrillation and heart valve disease: self-monitoring coagulation status using point-of-care coagulometers (the CoaguChek XS system and the INRatio2 PT/INR monitor). Costing statement. London (UK): National Institute for Health and Care Excellence (NICE); 2014 Sep. 10 p. (Diagnostics guidance; no. 14). Electronic copies: Available from the NICE Web site .
- Diagnostics Assessment Programme manual. London (UK): National Institute for Health and Care Excellence; 2011 Dec. 130 p. Electronic copies: Available from the NICE Web site .

Patient Resources

The following is available:

- Self-monitoring coagulation status in people on long-term vitamin K antagonist therapy who have atrial fibrillation or heart valve disease: point-of-care coagulometers (the CoaguChek XS system and the INRatio2 PT/INR monitor). Information for the public. London (UK): National Institute for Health and Care Excellence (NICE); 2014 Sep. (Diagnostics guidance; no. 14). Electronic copies: Available from the National Institute for Health and Care Excellence (NICE) Web site . Also available in Welsh from the NICE Web site .

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

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